

port, the location of said side port with respect to said point, the size of said side port in the axial direction of said needle being of such dimension that when said spinal needle is inserted in a conventional manner in a patient to effect delivery of an anesthetic, said side port is entirely located within the cerebrospinal space. --

REMARKS

Claims 16-22 were rejected under 35 USC 102(b) and 35 USC 112. The Examiner maintains that the recitation in the claims of locating the side port entirely within the cerebrospinal space and not located within the dura matter when the spinal needle is inserted for proper delivery of an anesthetic is functional. Claims 16-22 have been replaced with new claims 23 - 38 which more particularly identify with specificity the approximate size of the cerebrospinal space.

As is well known in the art, the cerebrospinal space is the space that surrounds the spinal column and is bounded on its outer edge by the arachnoid membrane. The present invention is the first spinal needle which enables effective administration of an anesthetic to the subdura by ensuring that the delivery port for the anesthetic is not in the dura matter, when the spinal needle is inserted and ready for delivery of anesthetic. The depth of the cerebrospinal space is conventionally known to one of ordinary skill in the art to be at least 2-4 mm. Claim 23 refers to a limitation that has sufficient specificity to one of ordinary skill in the art because one such person would know the approximate outer limit of the cerebrospinal space (depending on whether a child or an adult) and would select a spinal needle which would be so sized that the side port would be entirely within the cerebrospinal space and not extend to be in the dura matter.

Submitted herewith is a brochure of applicant showing the true size of the spinal needle, which materially contrasts with the sizes shown in the figures in the patent application. Submitted herewith, additionally, is a photograph of prior art needles which will be referred to hereinafter as well as the inventor's drawing of an early Whitacre needle.

The inventor is the first to have identified and provided a structure whereby an effective delivery port for the anesthesia is located solely within the cerebrospinal space. The prior art Sprotte needle referred to in the patent application and identified in the photograph illustrates how large the delivery port is and how the delivery port extends beyond the cerebrospinal space into the dura matter. This is also true with regard to a prior Whitacre spinal needle.

The drawing showing the earliest Whitacre needle produced over 50 years ago illustrates a spinal needle which was constructed using a simple drilling mechanism to drill a hole shown near the top of the needle to connect the lumen to deliver anesthesia. The size of the hole in Whitacre was materially smaller than the cross sectional area of the lumen, so that the anesthetic sprayed from the hole rather than being smoothly delivered. The size of the hole in Whitacre rendered the early device substantially unusable. Thereafter, Whitacre enlarged the side port to allow effective delivery of the anesthetic and located the side port such that it extended into the dura matter when the needle was inserted and ready for administration of anesthetic.

Within the confines of normal anatomy, it would be readily understood by one of ordinary skill in the art that the second outer edge of the side port of the present invention



will not extend into the dura matter when the needle properly is located for delivery of anesthesia. The skilled practitioner inserts the needle through "feel", and when there is a "popping", one of ordinary skill in the art knows that the dura has been traversed and the needle is approaching the proper location for administration of the anesthetic.

The recitation of the size of the cerebrospinal space is not intended to limit the scope of the invention nor to require that the present invention only be used on patients whose cerebrospinal space is at least 2 mm, but it is intended to provide specificity with regard to the dimensions to be achieved and expected by one of ordinary skill in the art. One of ordinary skill in the art would know the general size of the cerebrospinal space and would be able to locate the side port with respect to that space so that it would be totally located within the cerebrospinal space and be of a size at least equal to if not slightly greater than the lumen to effect proper delivery of the anesthetic.

Claim 23 incorporates limitations relating to the cross sectional area of the side port as well as the location of the outer edge of the side port with respect to the cerebrospinal space to provide a definite structure so that one of ordinary skill in the art could practice the invention as taught herein.

In view of the above, it is respectfully requested that a Notice of Allowance be issued.

A two month extension of the time for responding to the outstanding Action is requested and a check in the amount of \$190. is attached. If there are any additional fees due, the Examiner is requested to charge deposit account No. 02-2105 or refund any overpayment thereto.

Respectfully submitted,

Peter L. Berger
Peter L. Berger
Reg. No. 24,570

LEVISSON, LERNER, BERGER & LANGSAM
757 Third Avenue, Suite 2400
New York, New York 10017
212-486-7272

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